K112215
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HemCon Medical Technologies Europe
6 Courtyard Business Centre, Orchard Lane, Blackrock, Dublin, Ireland

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APR 12 2012

510(k) Summary

Trade Name:	HemCon GuardaGel™
Classification Name:	Dressing, Wound, Drug
Regulation No:	Unclassified
Product Code:	FRO
Predicate Device(s):	BloodSTOP™ (K072681) Seal-On™ Hemostatic Powder Spray (K010933)
Company Name:	HemCon Medical Technologies Europe Ltd.
Company Address:	6 Courtyard Business Centre, Orchard Lane, Blackrock, Co. Dublin, Ireland
Contact Person (Europe):	Máire Ní Beilliú R&D Manager and Quality Representative HemCon Medical Technologies Europe Ltd.
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Contact Person (US):	Kendra Rathkey Regulatory Manager HemCon Medical Technologies Inc.
Contact Phone:	+1-503-245 0459 x139
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Date of Preparation:	30 March 2012

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Description of the Device:

HemCon GuardaGel™ is intended for the management of wounds and for emergency external use in the temporary control of minor bleeding from the skin and other surface wounds where temporary control of bleeding is required. It is a homogenous aqueous, viscous opaque gel comprised of pectin, m•doc™ (HemCon's proprietary hemostatic oxidized cellulose formulation), potassium sorbate, glycerol and 5 %w/w ethanol. The gel comes in a sterile pre-filled syringe.

HemCon GuardaGel™ has not been evaluated for the control of traumatic or severe bleeding.

Intended Use:

Prescription: HemCon GuardaGel™ is intended for management of wounds and for emergency external use for the temporary control of minor bleeding from skin surface wounds.

OTC: HemCon GuardaGel™ First Aid is intended for management of wounds and for emergency external use for the temporary control of minor bleeding from minor topical cuts and lacerations.

Basis for Substantial Equivalence:

HemCon is claiming substantial equivalence of the proposed device to two predicate devices, Seal-On™ Hemostatic Spray (**K010933**) and BloodSTOP™ (**K072681**). Like HemCon GuardaGel™, both BloodSTOP™ and Seal-On™ contain plant sourced cellulose as a hemostatic agent. In the case of the HemCon Hemostatic Gel and Seal-On™ the plant sourced cellulose is HemCon's proprietary hemostatic agent micro-dispersed oxidized cellulose (m•doc™). The hemostatic agent in BloodSTOP™ is regenerated cotton cellulose.

HemCon GuardaGel™, BloodSTOP™ (**K072681**) and Seal-On™ Hemostatic Spray (**K010933**) have the same intended use, namely to provide temporary control of bleeding from the skin and other surface wounds. Both HemCon GuardaGel™ and BloodSTOP™ are intended for emergency and therapeutic use.

HemCon believes that the proposed device is substantially equivalent to the predicate devices and that the predicate devices adequately demonstrate the safety and efficacy of hemostats comprising a form of cellulose as the hemostatic agent

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Summary of Performance Testing:

Based on the performance testing of eleven individual lots of gel HemCon has demonstrated the ability to repeatedly produce product that the meets existing acceptance criteria.

Hemostatic Efficacy

The hemostatic efficacy of HemCon GuardaGel™ has been determined using an *in vitro* assay which evaluates the activation of the intrinsic pathway of the blood coagulation cascade. The assay is a spectrophotometric assay which measures the activity of the contact activation proteins, Factor XII and kallikrein. The HemCon Hemostatic Gel formulation has been shown to activate the contact phase enzymes of the intrinsic pathway of the blood coagulation cascade.

The hemostatic efficacy of the HemCon GuardaGel™ has also been demonstrated *in vivo* in rabbits. The average time for cessation of bleeding of wounds treated with HemCon GuardaGel™ was 23.1 s ± 5.8 s compared to 106.8 s ± 18.6 s for untreated wounds.

Biocompatibility

Biocompatibility has been demonstrated for the device according to ISO 10993 Categorization of the device by nature of body contact deduces HemCon GuardaGel™ is a surface-contacting device that contacts breached or compromised surfaces. The duration of contact may be prolonged at more than 24 hours, but no more than 30 days. Cytotoxicity, irritation and sensitization testing was performed.

Sterility

Sterility validations were completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Conclusion:

The conclusion drawn from the substantial equivalence argument and non-clinical performance data is that the proposed device is as safe and effective as the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 12 2012

HemCon Medical Technologies Europe Ltd
% HemCon Medical Technologies, Inc.
Ms. Kendra Rathkey
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223-4363

Re: K112215
Trade/Device Name: HemCon GuardaGel™
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 10, 2012
Received: February 13, 2012

Dear Ms. Rathkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HemCon Medical Technologies Europe
6 Courtyard Business Centre, Orchard Lane, Blackrock, Dublin, Ireland

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Applicant: HemCon Medical Technologies Europe Limited
510(k) Number: K112215
Device Name: HemCon GuardaGel™

Indications for Use – Rx Only:

HemCon GuardaGel™ is intended for management of wounds and for emergency external use for the temporary control of minor bleeding from skin surface wounds.

Indications for Use – OTC:

HemCon GuardaGel™ First Aid is intended for management of wounds and for emergency external use for the temporary control of minor bleeding from minor topical cuts and lacerations.

Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** ☒ (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kane for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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